



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/407,182	09/29/1999	DONALD L. SIEGEL	9596-43U1-(J)	2410

7590

04/06/2004

MORGAN, LEWIS & BOCKIUS, L.L.P.
1701 MARKET STREET
PHILADELPHIA, PA 19103

EXAMINER

BROWN, TIMOTHY M

ART UNIT	PAPER NUMBER
----------	--------------

1648

DATE MAILED: 04/06/2004

11

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/407,182

Applicant(s)

SIEGEL, DONALD L.

Examiner

Tim Brown

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 August 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-19 is/are pending in the application.
- 4a) Of the above claim(s) 20-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Art Unit: 1648

DETAILED ACTION

This Non-Final Office Action is responsive to Applicants' Amendment mailed August 6, 2002.

The status of the pending claims is as follows: the objection to claim 11 is withdrawn; the rejection of claims 10, 18 and 19 under 35 U.S.C. § 112, second paragraph is withdrawn; claims 10-19 are rejected under 35 U.S.C. § 112, first paragraph.

Claim Rejections - 35 USC § 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 11 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for detecting cell agglutination wherein a mixture of cells and inert particles is incubated prior to centrifugation,¹ does not reasonably provide enablement for a method for performing said method in the absence of an incubation step. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to perform the invention commensurate in scope with these claims.

A number of factors are considered in determining whether "undue experimentation" is required to make and use the invention. These factors include the

¹ The specification indicates Applicants' method is capable of identifying cell agglutination based on the distribution of phases in the microtubes depicted in Figure 6.

breadth of the claims, the nature of the invention, state of the prior art, and the amount of direction provided by the inventor. *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404.

The nature of Applicants' invention relates to a method for detecting cell agglutination wherein a mixture of cells, cell/virus complexes and antibodies bound to inert particles are combined and subjected to centrifugation. An analysis of the relative distribution of the mixture components after centrifugation indicates the level of agglutination between the components of the mixture.

The breadth of Applicants' claims supports an interpretation wherein the mixture is centrifuged without an incubation step that allows the cell/virus complexes to agglutinate with the antibodies that are bound to the inert particles. It is known in the art that detecting the relative distribution of agglutinated components from a reaction mixture requires an incubation step wherein agglutination is allowed to occur (See Setcavage et al., US Patent No. 5,491,067, col. 1, lines 26-39).

Applicants' specification fails to detail how an agglutination assay, which relies on centrifugation and the detection of distinct phases, can be performed without performing an incubation step prior to centrifugation. In fact, Applicants' specification dictates that their method involves an incubation step prior to subjecting the mixture to centrifugation (see Specification, p. 24, line 23).

Based on the foregoing, it appears the breadth of Applicants' claims encompasses the centrifugation of the mixture without performing an incubation step. Prior art agglutination assays require an incubation step prior to centrifugation. Applicants' disclosure fails to describe how their method can be performed without

Art Unit: 1648

performing the critical incubation step. Accordingly, undue experimentation is required in order for one of ordinary skill to make and use Applicants' invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. Claim 11 lacks the essential step of incubating the mixture of cell/virus complexes with the inert particles prior to centrifugation. Appropriate correction is required.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tim Brown whose telephone number is (571) 272-0773. The examiner can normally be reached on Monday - Friday, 8am - 5pm.

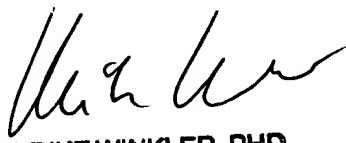
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1648

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Tim Brown
Examiner
Art Unit 1648

tmb


ULRIKE WINKLER, PHD.
PATENT EXAMINER 4/5/04